

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

JAMES M. NIELSEN, M.D.

Plaintiff,

VS.

ALCON, INC., ET AL.

Defendants.

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NO. 3-08-CV-2239-B-BD

**FINDINGS AND RECOMMENDATION OF THE
UNITED STATES MAGISTRATE JUDGE**

This patent case is before the court on cross-motions for summary judgment. Defendants Alcon, Inc. and Alcon Laboratories, Inc. ("Alcon") seek summary judgment on the issues of infringement and willful infringement, and on their affirmative defenses of invalidity, laches, estoppel, and failure to mark. Plaintiff James M. Nielsen, M.D. ("Nielsen") moves for partial summary judgment as to the affirmative defenses of invalidity due to anticipation under 35 U.S.C. § 102(a) & (b), laches, and estoppel. For the reasons stated herein, both motions should be denied.

I.

Plaintiff is the owner and named inventor of U.S. Patent No. 5,158,572 ("the '572 Patent"), entitled "Multifocal Intraocular Lens." (See Def. MSJ App., Exh. 4 at 116). Simply stated, the patented device is an artificial lens, comprised of a substantially circular central region surrounded by multiple concentric ring regions providing a variety of optical powers, that can be surgically implanted inside a human eye to correct both near and distance vision. (See *id.*, Exh. 4 at 119-20). The device claims to provide vision correction closely approximate to the range of a natural lens by

relying on the inherent ability of the nervous system to selectively perceive one of two or more optical inputs. (*See id.*, Exh. 4 at 120).

Defendants manufacture and sell a line of intraocular lenses ("IOLs") known as the ReSTOR® IOL. (*See id.*, Exh. 5 at 126-27). The ReSTOR® IOL is comprised of an inner "apodized diffractive region" and an outer "refractive region." (*See id.*, Exh. 5 at 126).¹ According to promotional literature published by defendants, the apodized diffractive region "comprises 12 concentric steps of gradually decreasing . . . step heights that allocate energy based on lighting conditions and activity, creating a full range of quality vision – near to distant." (*Id.*) (emphasis in original). The refractive region, which surrounds the apodized diffractive region, "directs light to a distance focal point for larger pupil diameter, and is dedicated to distance vision." (*Id.*) (emphasis in original). Defendants advertise the ReSTOR® IOL to cataract patients "who desire near, intermediate, and distance vision" without glasses. (*Id.*, Exh. 5 at 126-27).

In this action, plaintiff sues defendants for direct and contributory infringement of the '572 Patent. (*See* Plf. Orig. Compl. at 3-4, ¶¶ 11-12). Defendants deny any infringement and contend that the patent-in-suit is invalid due to anticipation by prior art, for obviousness, and for lack of a written description. (*See* Def. Ans. at 2-4). Both sides now move for summary judgment on the affirmative defense of invalidity due to anticipation and various defenses related to damages. Defendants also seek summary judgment on the threshold issue of infringement and their other invalidity defenses.

¹ "Refraction" and "diffraction" refer to different optical principles. "Refraction" occurs when light enters a medium that causes its speed to change, thus bending the light wave. (Def. MSJ App., Exh. 1 at 16; *see also* Plf. MSJ App., Exh. 93 at 854). "Diffraction" occurs when light bends as it passes the edge of an object. (Def. MSJ App., Exh. 1 at 17; *see also* Plf. MSJ App., Exh. 93 at 858). Both principles have been applied in the field of ophthalmology to improve human vision. (*See* Def. MSJ App., Exh. 1 at 19).

II.

Summary judgment is proper when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The substantive law determines which facts are material. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247, 106 S.Ct. 2505, 2509-10, 91 L.Ed.2d 202 (1986). In a patent case, a defendant who seeks summary judgment on an affirmative defense must establish "beyond peradventure" all of the essential elements of the defense to warrant judgment in its favor. *See Mannatech, Inc. v. Glycobiotics Int'l Inc.*, No. 3-06-CV-0471-BD, 2007 WL 4386244 at *1 (N.D. Tex. Dec. 14, 2007) (citing cases). By contrast, a defendant who seeks summary judgment on the issue of infringement, or a plaintiff who seeks summary judgment on an affirmative defense, need only point to the absence of a genuine fact issue. *See Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001). Once the movant meets its initial burden, the burden shifts to the nonmoving party to produce evidence or designate specific facts in the record showing the existence of a genuine issue for trial. *See Mannatech*, 2007 WL 4386244 at *1. The parties may satisfy their respective burdens by tendering depositions, affidavits, and other competent evidence. *Id.* All evidence must be viewed in the light most favorable to the party opposing the motion. *Id.*

A.

Plaintiff contends that the intraocular lens manufactured and sold by defendants under the brand name ReSTOR® directly infringes Claim 10 of the '572 Patent, both literally and under the doctrine of equivalents. A patent is infringed if every limitation set forth in a claim is present in an accused product. *See Seal-Flex, Inc. v. Athletic Track and Court Constr.*, 172 F.3d 836, 842 (Fed. Cir. 1999); *Jurgens v. McKasy*, 927 F.2d 1552, 1560 (Fed. Cir.), *cert. denied*, 112 S.Ct. 281 (1991).

Where literal infringement is alleged, the patentee must prove that the accused product contains each limitation of an asserted claim. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir.), *cert. denied*, 121 S.Ct. 484 (2000). "If any claim limitation is absent from the accused [product], there is no literal infringement as a matter of law." *Id.*; *see also Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir.), *cert. denied*, 124 S.Ct. 464 (2003). To prove infringement under the doctrine of equivalents, a patentee must demonstrate that the accused product contains each limitation of the claim or its equivalent. *See Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1382 (Fed. Cir. 2009). "An element in the accused product is equivalent to a claim limitation if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Eagle Comtronics, Inc. v. Arrow Comm. Labs., Inc.*, 305 F.3d 1303, 1315 (Fed. Cir. 2002), *cert. denied*, 123 S.Ct. 995 (2003). The test for equivalence is whether "the accused product performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product." *Alcohol Monitoring Sys., Inc. v. Actsoft, Inc.*, 414 Fed.Appx. 294, 300, 2011 WL 201494 at *5 (Fed. Cir. Jan. 24, 2011), *quoting Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1312 (Fed. Cir. 2009).

1.

The '572 Patent claims a multifocal intraocular lens for implantation in the human eye having a plurality of concentrically arranged regions alternately powered for differing vision ranges. Claim 10 of the patent reads:

A multifocal lens adapted for intraocular implantation in a human eye comprising a one piece transparent lens body having a substantially circular central region having a first optical power; and a plurality of

concentric ring regions coaxially surrounding said central region, the first innermost of said ring regions having a second optical power different from said first optical power, and a second subsequent ring region having a third optical power different from the optical power of the innermost ring region and different from the optical power of the central region.

(See Def. MSJ App., Exh. 4 at 120). In a prior action before a different judge, the court construed certain terms used in Claim 10 of the '572 Patent. One of the disputed claim terms, "optical power," was construed by the court to mean "the index of refraction divided by focal length." *Nielsen v. Advanced Medical Optics*, No. 3-05-CV-0018-L, Mag. J. F&R at 15, 28 (N.D. Tex. Aug. 30, 2006), *rec. adopted*, (N.D. Tex. Mar. 16, 2007) ("the AMO Litigation"). The parties in the instant case have agreed to be bound by that claim construction ruling. (See Doc. #32).

2.

The central dispute regarding infringement is whether the ReSTOR® IOL manufactured and sold by defendants has three or more "optical powers," as taught by Claim 10 of the '572 Patent, or whether the accused product has only two "optical powers." Defendants rely on measurements made by their expert, Dr. Allen L. Cohen, an optometrist, to prove that the ReSTOR® lens generates only two focal points and, thus, does not infringe Claim 10 of the patent. (See Def. MSJ App., Exh. 1 at 12-14). Plaintiff counters with a report by Dr. Duncan T. Moore, an optical engineer, who concludes that the ReSTOR® lens has "at least three focal lengths" and "at least three optical powers[.]" (See Plf. MSJ App., Exh. 93 at 874, ¶ 89). For summary judgment purposes, this "battle of the experts" focuses on whether the opinions of Dr. Moore are admissible under Fed. R. Civ. P. 702 and *Daubert*. If admissible, defendants tacitly concede that there is a genuine issue of material fact as to infringement. See *Metro. Life Ins. Co. v. Bancorp Servs., LLC*, 527 F.3d 1330, 1338-39 (Fed. Cir.

2008) (conflict in expert testimony creates a genuine issue of material fact making summary judgment inappropriate). However, defendants maintain that Dr. Moore's opinions are not reliable because his infringement theory is based on an unverified theoretical model, rather than physical testing, and unsubstantiated assumptions. As a result, defendants contend that they are entitled to summary judgment on the issue of infringement.

a.

The admissibility of expert testimony in a patent case is a procedural issue governed by the law of the regional circuit in which the district court resides. *See Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1390-91 (Fed. Cir. 2003). In the Fifth Circuit, Fed. R. Evid. 702 is the starting point for determining whether expert testimony is admissible at trial. This rule provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702. Effective December 1, 2000, Rule 702 was amended to incorporate the principles first articulated by the Supreme Court in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). *See* FED. R. EVID. 702, adv. comm. notes (2000). Under *Daubert*, expert testimony is admissible only if the proponent demonstrates that: (1) the expert is qualified; (2) the evidence is relevant to the suit; and (3) the evidence is reliable. *See Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988-89 (5th Cir. 1997). The trial court is charged with making this

preliminary determination under Fed. R. Evid. 104(a).² *Andrade Garcia v. Columbia Medical Cntr. of Sherman*, 996 F.Supp. 617, 620 (E.D. Tex. 1998); *see also* FED. R. EVID. 702, adv. comm. notes (2000).

Daubert lists five non-exclusive factors to consider when assessing the scientific validity or reliability of expert testimony:

1. Whether the theory or technique has been tested;
2. Whether the theory or technique has been subjected to peer review and publication;
3. The known or potential rate of error of the method used;
4. The existence and maintenance of standards and controls in the methodology; and
5. Whether the theory or method has been generally accepted by the scientific community.

Daubert, 113 S.Ct. at 2796-97. This analysis focuses on the reasoning or methodology employed by the expert, not the ultimate conclusion. *Watkins*, 121 F.3d at 989. The purpose of such an inquiry is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Skidmore v. Precision Printing and Packaging, Inc.*, 188 F.3d 606, 618 (5th Cir. 1999), *quoting Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152, 119

² Fed. R. Evid. 104(a) provides:

Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

FED. R. EVID. 104(a).

S.Ct. 1167, 1176, 143 L.Ed.2d 238 (1999). Thus, the court "must review only the reasonableness of the expert's use of such an approach, together with his particular method of analyzing the data so obtained, to draw a conclusion regarding the specific matter to which the expert testimony is directly relevant." *American Tourmaline Fields v. International Paper Co.*, No. 3-96-CV-3363-D, 1999 WL 242690 at *2 (N.D. Tex. Apr. 19, 1999), citing *Kumho Tire*, 119 S.Ct. at 1177.

The test of reliability is necessarily a flexible one. As the Supreme Court has recognized, the *Daubert* factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Kumho Tire*, 119 S.Ct. at 1175; see also *Watkins*, 121 F.3d at 988-89 ("Not every guidepost outlined in *Daubert* will necessarily apply to expert testimony[.]"). A trial court has wide latitude in deciding how to determine reliability, just as it has considerable discretion with respect to the ultimate reliability determination. *Kumho Tire*, 119 S.Ct. at 1176. Moreover, "the rejection of expert testimony is the exception rather than the rule." See FED. R. EVID. 702, adv. comm. notes (2000). *Daubert* did not work a seachange over federal evidence law, and "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." See *id.*, quoting *United States v. 14.38 Acres of Land, More or Less, Situated in Leflore County, Miss.*, 80 F.3d 1074, 1078 (5th Cir. 1996). Even after *Daubert*, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 113 S.Ct. at 2798; see also *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994), *cert. denied*, 115 S.Ct. 1253 (1995) ("The grounds for the expert's opinion merely have to be good, they do not have to be perfect.").

Many courts are reluctant to entertain *Daubert* challenges at the summary judgment stage.

As the First Circuit noted:

The fact that *Daubert* can be used in connection with summary judgment motions does not mean that it should be used profligately. A trial setting normally will provide the best operating environment for the triage which *Daubert* demands . . . Because the summary judgment process does not conform well to the discipline that *Daubert* imposes, the *Daubert* regime should be employed with great care and circumspection at the summary judgment stage.

Cortes-Irizarry v. Corporacion Insular De Seguros, 111 F.3d 184, 188 (1st Cir. 1997); *see also Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417-18 (3rd Cir. 1999). A proper *Daubert* analysis requires a complex factual inquiry that is difficult, if not impossible, to conduct on a truncated record. Indeed, a hearing under Rule 104(a) is often required to determine the admissibility of expert testimony. *See Padillas*, 186 F.3d at 417. Therefore, the court will conduct only a preliminary review to determine whether Dr. Moore's expert opinions are admissible for summary judgment purposes. *See Alcan Aluminum Corp. v. BASF Corp.*, 133 F.Supp.2d 482, 493 (N.D. Tex. 2001).

b.

Dr. Moore, a Professor of Optical Engineering at the University of Rochester, was retained by plaintiff to test four sample ReSTOR® lenses provided by defendants -- SN6AD1, SN6AD3, SA60D3, and SN60D3 ("the accused lenses") -- in order to give an expert opinion on infringement. (See Plf. MSJ App., Exh. 93 at 846-47, ¶¶ 1-7, 9 & 865, ¶ 63). In his report, Dr. Moore explains that he used three basic testing methodologies to obtain the optical powers of the central region and the rings surrounding the central region of the accused lenses: (1) surface profile measurements along a radial direction; (2) surface profile measurements along multiple radial directions; and (3) optical power calculations and raytracing using Alcon engineering data. (*Id.*, Exh. 93 at 865, ¶ 62). Unlike

defendants' expert, Dr. Moore did not directly measure the focal length of the accused lenses. (*See* Def. MSJ App, Exh. 9 at 219, ¶ 48). Instead, he used a white light interferometer³ to determine the optical powers of the central region and the rings surrounding the central region. (*See* Plf. MSJ App., Exh. at 93 at 865, ¶¶ 61-62 & 866, ¶¶ 64, 68). Initially, Dr. Moore measured the radius of curvature for the central region, the first ring region, the fifth ring region, and the outer region of the sample lenses. (*Id.*, Exh. 93 at 866, ¶ 64). Later, he measured the radius of curvature for all rings. (*Id.*). The interferometer collected several thousand data points to calculate the radius of curvature for each of the various ring regions of the accused lenses. (*Id.*, Exh. 93 at 867, ¶ 72 & 868, ¶ 74).

Dr. Moore states in his report that the optical power of a lens can be calculated knowing the radii of curvature of the first and second surfaces, the axial thickness of the lens, and several indices of refraction of the lens. (*Id.*, Exh. 93 at 868-69, ¶ 75). Based on engineering data and other information provided by defendants, including radii of curvature measurements, Dr. Moore calculated the optical powers of the accused lenses using a mathematical formula known as the "Kingslake equation." (*Id.*, Exh. 93 at 854, ¶ 36 & 865-66, ¶¶ 62, 65). He also generated raytracing diagrams using LightTools, a commercial software package, to illustrate the opinions in his report. (*Id.*, Exh. 93 at 869, ¶ 78). One of those opinions is that the accused lenses "have multiple refractive ring regions which also provide diffractive properties." (*Id.*, Exh. 93 at 874, ¶ 89). According to Dr. Moore, undiffracted light passing through the accused lenses will be refracted to different focal lengths independent of the diffractive properties of the lenses. (*Id.*). Thus, Dr. Moore concludes that the accused lenses "have at least three focal lengths -- and at least three optical powers -- whether

³ An interferometer measures the departure of an optical surface from a plane and has built-in software that calculates both the tilt of the surface and the radius of curvature of the surface. (*See* Plf. MSJ App., Exh. 93 at 867, ¶ 70).

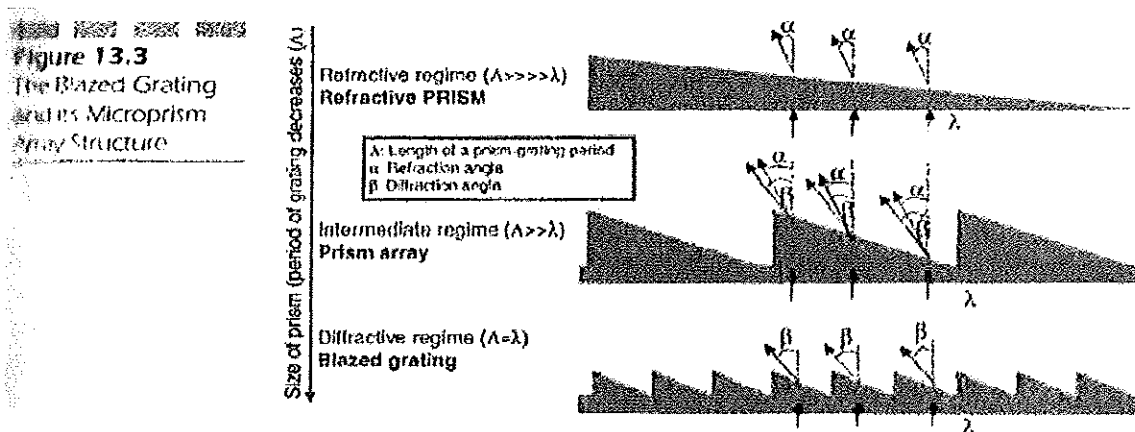
the diffractive properties are present or not." (*Id.*). Dr. Moore further states that each ring region has a particular "optical power" that differs from that of the central region and the first ring region. (*See id.*, Exh. 93 at 915, ¶ 229; 917, ¶ 237; 920, ¶ 246; 922, ¶ 255). As a result of his testing, Dr. Moore concludes that the accused lenses literally infringe Claim 10 of the '572 Patent because each lens "has a second subsequent ring region . . . having the same or substantially the same optical power across that region where the index of refraction divided by focal length for that region is different than that for the central region and the innermost ring region." (*Id.*, Exh. 93 at 922, ¶ 256).

c.

Defendants argue that physical testing performed by their expert, Dr. Cohen, definitively proves that the accused lenses generate only two focal points, and therefore do not infringe Claim 10 of the '572 Patent, whereas plaintiff has failed to provide any physical evidence of literal infringement. In an effort to discredit the opinions of Dr. Moore, defendants attack his "radius of curvature theory" as unreliable because it is based on a mathematical equation that "has never been verified in any real-world setting." (*See* Def. MSJ Br. at 7). The court initially observes that an expert is not required to perform direct physical testing on an accused device in order to prove infringement. *See Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1219 (Fed. Cir.), *cert. denied*, 127 S.Ct. 599 (2006) (jury entitled to rely on circumstantial evidence of infringement drawn from engineering manual over direct evidence from an expert who tested the accused product). Here, Dr. Moore calculated the optical power of the accused lenses using the "Kingslake equation." (*See* Plf. MSJ App., Exh. 93 at 854, ¶ 36). Standards promulgated by the International Standards Organization ("ISO") identify the Kingslake equation as an accepted method for calculating optical power. (*Id.*, Exh. 56 at 509-10). Even defendants acknowledge that the ISO "provides industry-wide

standards for products in a number of industries, including the IOLs at issue in the present case." (Def. MSJ Br. at 6 n. 24). The court has little difficulty concluding, at least at the summary judgment stage, that this methodology was reliable. That defendants propose their own testing methodology does not undermine the reliability of Dr. Moore's opinions to the point of exclusion. *See Reedhycalog UK, Ltd. v. Baker Hughes Oilfield Operations Inc.*, No. 6-06-CV-222, 2008 WL 5572567 at *9 (E.D. Tex. May 20, 2008).

In a related argument, defendants challenge as "unsupported and false" a basic assumption underlying the methodology employed by Dr. Moore -- that some of the light passing through the diffractive region of the accused lenses is not diffracted. (See Def. MSJ Br. at 6, 10). Plaintiff counters with an excerpt from a scientific textbook co-authored by Robert E. Fischer, *Optical System Design*,⁴ which appears to support the assumption made by Dr. Moore. (See Plf. MSJ App., Exh. 14 at 181-82). As best the court understands this excerpt, when the spacing of regions is larger in size than the wavelength of light, both refraction and diffraction exist. Fischer uses the following diagram, Figure 13.3, to illustrate this principle:



⁴ R.E. Fischer, B. Tadic-Galeb & P.R. Yoder, *Optical System Design* (2d ed. 2008).

(*Id.*, Exh. 14 at 181). According to the Fischer text, "[a]s one looks closer at a blazed grating, one can consider the various periods of this grating as many *individual refractive microprisms*, and therefore apply not only the grating equation . . . *but also Snell's law⁵ of refraction to each individual microprism[.]*" (*Id.*) (emphasis added). So, while lenses will bend light primarily by refraction or diffraction at the extremes, the transition between those extremes is not binary, allowing for both refraction and diffraction in an "Intermediate regime." Dr. Moore expressly relies on the Fischer text, including Figure 13.3, to support his infringement theory. In a supplemental expert report, Dr. Moore explains:

Figure 13.3 shows how, in the "Refractive regime," where the prism period is significantly greater than the wavelength of light [], any amount of diffraction is negligible. And in the "Diffractive regime," where the prism period is equal to the wavelength of light [], any amount of refraction is negligible. However, in the "Intermediate regime," where the prism period is much greater than the wavelength of light [], both diffraction due to the grating and refraction due to the refractive microprism must be considered, as I did in my prior Reports. These refractive microprisms are equivalent to the refractive surface curvatures of each of the ring regions of the ReSTOR IOLs, which are also at a period in the "Intermediate regime." Because each ring region has a different radii of curvature, each ring region will have a different refractive optical power associated with that region -- as I discussed in my prior Reports, as confirmed by LightTools, and as verified by scientific literature in the field of optics.

(*Id.*, Exh. 95 at 1288 at ¶ 31). Thus, there is at least some scientific authority to support Dr. Moore's assumption that some of the light passing through the diffractive regions of the accused lenses is not diffracted.

The other *Daubert* challenges made by defendants are also without merit. Incredibly, defendants argue that their own engineering data, used by Dr. Moore in his mathematical

⁵ Snell's law predicts the amount of refraction at a given optical interface. (See Plf. MSJ App., Exh. 14 at 181).

calculations and computer models, is not reliable because it represents "aspirational targets for manufacturing ReSTOR® lenses." (Def. MSJ Br. at 9). An attack on data relied on by an expert generally goes to the weight to be given, rather than the admissibility of, his testimony. *Anascope, Ltd. v. Microsoft Corp.*, No. 9-06-CV-158, 2008 WL 7180757 at *2 (E.D. Tex. Apr. 28, 2008); *see also Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004), *quoting 14.38 Acres of Land*, 80 F.3d at 1077 ("As a general rule, questions relating to the bases and sources of an expert's opinion affect the *weight* to be assigned that opinion rather than its *admissibility* and should be left for the jury's consideration."). Defendants also argue that scientific information cited by plaintiff in the *AMO* Litigation contradicts Dr. Moore's opinion that the ReSTOR® lens has three optical powers. (*See* Def. MSJ Br. at 11-12). It is true that Dr. Jim Schweigerling, a former student of Dr. Moore who was retained by plaintiff as a consultant in the *AMO* Litigation, authored a presentation depicting the ReSTOR® lens with one first order power and one zeroth-order power, for a total of only two powers. (*See* Def. MSJ App., Exh. 52 at 849-50). However, that a different expert may have taken a contrary position in prior litigation does not undermine the reliability of Dr. Moore's opinion in *this case*.

Plaintiff has adduced sufficient evidence at the summary judgment stage to persuade the court that the methodology employed by Dr. Moore is reliable. Without suggesting a view of whether that methodology will withstand a *Daubert* challenge after a more rigorous examination at a Rule 104(a) hearing, either before or during trial, defendants are not entitled to summary judgment on this ground.

d.

Nor are defendants entitled to summary judgment on plaintiff's claim for infringement under the doctrine of equivalents. To prove infringement under the doctrine of equivalents, "a patentee must . . . provide particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused device or process, or with respect to the function, way, result test[.]" *See AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1328-29 (Fed. Cir.2007), *quoting Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996). The same rule applies in the summary judgment context. *Id.* In his expert report, Dr. Moore explains:

The Accused Devices have at least two ring regions, the innermost of which has an optical power different from the central region. Having a central region with adjoining optical ring regions of the exact same optical power would not change the function of the lens because these adjoining regions can be functionally considered as part of the central region. The lenses still have multiple additional ring regions with additional optical powers different from the central region, so the intended functions of the '572 patent are still met by the Accused Devices.

(*Id.*, Exh. 93 at 922-23, ¶ 257). Defendants object to this opinion as "irrelevant" because the ReSTOR® lens has only two optical powers. (*See* Def. MSJ Br. at 13). As previously discussed, whether the accused lenses have two or three optical powers is a disputed fact that must be determined by a jury after a trial on the merits. Therefore, summary judgment is not proper.

B.

Defendants also seek summary judgment on their affirmative defenses that the '572 Patent is invalid due to anticipation, obviousness, and for lack of a written description. "A patent is presumed valid." *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir.

2002), *quoting* 35 U.S.C. § 282. To overcome this presumption of validity, the party challenging a patent must prove facts establishing invalidity by clear and convincing evidence. *Id.* Where, as here, the alleged infringer moves for summary judgment on an invalidity defense, it "must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001), *citing Anderson*, 106 S.Ct. at 2513-14. Once the alleged infringer meets this burden, the patent holder must present evidence, by affidavit or otherwise, creating a genuine issue of material fact for trial. *See D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1150 (Fed. Cir. 1983).

1.

Defendants contend that the '572 Patent is invalid due to anticipation by prior patents under 35 U.S.C. § 102(e).⁶ This statute provides, in pertinent part:

A person shall be entitled to a patent unless --

* * * *

the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent filed in the United States before the invention by the applicant for patent[.]

35 U.S.C. § 102(e). A claim is anticipated when "the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Spanston*,

⁶ In their summary judgment reply brief, defendants stipulate that the prior art references cited by plaintiff in his cross-motion for summary judgment do not anticipate Claim 10 of the '572 Patent under 35 U.S.C. § 102(a) & (b). (*See* Def. MSJ Repl. Br. at 23 n.80). In view of that stipulation, plaintiffs' cross-motion for partial summary judgment on that ground should be denied as moot.

Inc. v. International Trade Comm'n, 629 F.3d 1331, 1356 (Fed. Cir. 2010), *pet. for cert. filed*, Jul. 27, 2011 (Nos. 10A1202, 11-127 & 11-128), *quoting Advanced Display Systems, Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000), *cert. denied*, 121 S.Ct. 1226 (2001). Anticipation is a question of fact. *See Zenith Elec. Corp. v. PDI Comm. Sys., Inc.*, 522 F.3d 1348, 1357 (Fed. Cir. 2008). However, anticipation may be resolved on summary judgment if there is no genuine issue of material fact such that no reasonable jury could find that the patent-in-suit was not anticipated. *Id.*, *citing Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327 (Fed. Cir. 2001).

a.

A reference patent anticipates an invention under section 102(e) only if the effective filing date of the reference patent is before the date of the invention. *Spansion*, 629 F.3d at 1356, *citing In re Mathews*, 56 CCPA 1033, 408 F.2d 1393 (1969). The date of the invention is presumed to be the date the inventor files his patent application. *See Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000), *cert. denied*, 121 S.Ct. 1607 (2001); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986), *cert. denied*, 107 S.Ct. 1606 (1987). However, a patentee may overcome this presumption with evidence that shows an earlier date of invention. *See Dow Chem. Co. v. Halliburton Co.*, 631 F.Supp. 666, 704 (N.D. Miss.1985), *aff'd*, 790 F.2d 93 (Fed. Cir. 1986). To prove an earlier invention date, a party must show either an earlier reduction of the invention to practice or an earlier conception and diligence in reduction to practice. *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001); *see also Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993) (priority of invention "goes to the first party to reduce an invention to practice unless the other party can show that it was the first

to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice.").

"Conception" is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice. *See Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). The idea must be "so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994), *cert. denied*, 116 S.Ct. 771 (1996). A "reduction to practice" can be either a constructive reduction to practice, which occurs when a patent application is filed, or an actual reduction to practice. *Cooper*, 154 F.3d at 1327. "Diligence in reduction to practice" can be shown by a variety of activities. *See Brown v. Barbacid*, 436 F.3d 1376, 1380 (Fed. Cir. 2006) (citing cases). The basic inquiry is whether the applicant was reasonably diligent in proceeding toward an actual or constructive reduction to practice. *Id.*

Where a party seeks to prove an earlier invention date through the oral testimony of an inventor, it must produce sufficient independent evidence corroborating that testimony. *See Shu-Hui Chen v. Bouchard*, 347 F.3d 1299, 1309 (Fed. Cir. 2003). "Sufficiency of corroboration is determined by using a 'rule of reason' analysis, under which all pertinent evidence is examined when determining the credibility of an inventor's testimony." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1170 (Fed. Cir. 2006); *see also Cooper*, 154 F.3d at 1331, *citing Berges v. Gottstein*, 618 F.2d 771, 776 (CCPA 1980) ("[E]ach corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive."). Corroborating evidence may take many forms. Reliable evidence of corroboration preferably comes from documents and records made

contemporaneously with the inventive process. *See Linear Technology Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1327 (Fed. Cir. 2004). But circumstantial evidence of an independent nature also may corroborate inventor testimony. *Id.*; *see also Sandt Technology, Ltd. v. Resco Metal and Plastics Corp.*, 264 F.3d 1344, 1351 (Fed. Cir. 2001).

b.

In their opening brief, defendants identify three patents that predate September 10, 1987 -- the date plaintiff filed his application for the '572 Patent:

<u>Patent No.</u>	<u>Inventor</u>	<u>Application Date</u>
U.S. Patent No. 4,898,461	Valdemar Portney	June 1, 1987
U.S. Patent No. 4,769,033	Lee T. Nordan	July 2, 1987 ⁷
U.S. Patent No. 4,795,462	Dennis T. Grendahl	August 24, 1987

(*See* Def. MSJ Br. at 20-25 & Def. MSJ App., Exh. 21 at 499, Exh. 22 at 514, Exh. 26 at 566).

Plaintiff counters that he is entitled to an invention date earlier than September 10, 1987, because he conceived of the invention embodied by Claim 10 of the '572 Patent by at least February 19, 1982, and thereafter worked diligently to reduce the invention to practice. (*See* Plf. MSJ Br. at 37-40). At his deposition, plaintiff testified that sometime in the late 1970s or early 1980s, he conceived of a multi-concentric, coaxial IOL design that would allow patients to see near, far, and intermediate distances at the same time. (*See* Plf. MSJ App., Exh. 69 at 600). Around that time, plaintiff constructed a prototype of his multifocal lens design in his garage and tested the design in someone

⁷ Plaintiff argues that the Nordan patent is entitled to a priority date of August 24, 1987, not July 2, 1987, because the earlier application "does not contain all of the disclosures that Alcon and Dr. Cohen rely on for invalidity[.]" (*See* Plf. MSJ Br. at 36). Even if the court gives the Nordan patent a priority date of July 2, 1987, as advocated by defendants, there is still a fact issue as to whether plaintiff conceived the invention embodied by Claim 10 of the '572 Patent and worked diligently to reduce that invention to practice before the application for the Nordan patent was filed.

else's kitchen. (*Id.*, Exh. 69 at 600-01; *see also* Def. MSJ App., Exh. 18 at 436). Plaintiff demonstrated his prototype lens to Keith Yeisley, the former president of a company that made micro-surgical instruments for the eye. (*See* Def. MSJ App., Exh. 18 at 439). After testing his design, plaintiff contacted an attorney to determine if his idea was patentable. (*Id.*, Exh. 18 at 436). Plaintiff later hired a lawyer to write a patent application for his invention. (*See id.*, Exh. 18 at 442, 444).

To corroborate his testimony, plaintiff points to the deposition of Keith Yeisley, who testified that plaintiff discussed his idea for a multifocal IOL during a meeting on February 19, 1982. (*See* Plf. MSJ App., Exh. 70 at 611-12, 615-17). According to Yeisley, plaintiff described the IOL as having "several 'concentric circles'" that would offer a patient the ability to "see things farther away, closer, and midway." (*See id.*, Exh. 70 at 616 & Exh. 71 at 626). Notes taken by Yeisley at the meeting -- which are dated "2-19-1982" -- include a diagram of a lens with three concentric circles: an inner circle "for reading," an outer circle "for distance," and a middle circle "for in-between." (*See id.*, Exh. 71 at 626). Yeisley said that he met with plaintiff approximately two weeks after their initial meeting on February 19, 1982, at which time plaintiff produced a rough model of his multifocal IOL. (*See id.*, Exh. 70 at 617; *see also* Def. MSJ App., Exh. 17 at 411-13). Plaintiff also relies on a letter from his former attorney, Marina Larson, dated August 19, 1987, transmitting to him an application for the '572 Patent "in final form." (*See* Plf. MSJ App., Exh. 12 at 132-48). In an affidavit authenticating the letter, Larson confirms that she sent the patent application to plaintiff on or about August 19, 1987, "although I have no present recollection of writing or sending this letter or other details of the representation." (*Id.*, Exh. 12 at 130-31, ¶ 4).⁸

⁸ Defendants object that Larson is not a proper custodian under Fed. R. Civ. P. 803(6), the business records exception to the hearsay rule, because she left her law firm in 1993 and the firm dissolved sometime thereafter. (*See* Def. MSJ Br. at 19 n. 78). The objection is overruled. A business record can be authenticated by the testimony of a "custodian" or

Defendants object that the evidence cited by plaintiff to corroborate his testimony regarding an earlier date of invention is "insufficient." (*See* Def. MSJ Br. at 16-19). In particular, defendants argue that nothing in Yeisley's deposition testimony or his notes mentions whether plaintiff's invention included a one-piece transparent lens body, which is an explicit limitation of Claim 10. (*Id.* at 16-17). Defendants also point out that it took plaintiff more than five years to reduce his invention to practice -- a delay that undermines his claim of diligence and demonstrates that his conception was not "so clearly defined" that only ordinary skill would be necessary to reduce it to practice. (*Id.* at 17-19). The court disagrees. Viewed in the light most favorable to plaintiff, Yeisley's diagram can be reasonably interpreted as depicting a single lens body. (*See* Plf. MSJ App., Exh. 71 at 626). Further, proof of reasonable diligence does not require that a party work constantly on an invention. *See Bey v. Kollonitsch*, 806 F.2d 1024, 1028 (Fed. Cir. 1986). That Larson sent plaintiff a patent application "in final form" for filing on or about August 19, 1987, supports an inference that plaintiff and his attorney were diligently working to reduce the invention to practice for a reasonable time prior to that date. *See Virginia Elec. & Lighting Corp. v. National Serv. Indus.*, 230 F.3d 1377 (Table), 2000 WL 12729 at *5 (Fed. Cir.), *cert. denied*, 120 S.Ct. 2743 (2000) (in summary judgment context, court must draw all reasonable inferences from the evidence in favor of the non-movant).

"other qualified witness." An "other qualified witness" is anyone "who can explain the record keeping of the organization and vouch that the requirements of Rule 803(6) are met." *Travland v. Ector Co.*, 39 F.3d 319 (Table), 1994 WL 612342 at *4 (5th Cir. Oct. 20, 1994). In her affidavit, Larson states that: (1) she was an attorney with the law firm of Brumbaugh, Graves, Donohue & Raymond in 1987; (2) it was part of the regular and ordinary business practices of the firm to draft and send patent applications and transmittal letters to their clients; and (3) the August 19, 1987 letter, signed by her, and the accompanying patent application were sent to plaintiff. (*See* Plf. MSJ App., Exh. 12 at 130, ¶¶ 3-4). This is sufficient to satisfy the requirements of Rule 803(6).

At a minimum, there is a genuine issue of material fact as to whether plaintiff conceived of the invention embodied by Claim 10 of the '572 Patent before the filing dates of the Portney, Grendahl, and Nordan patent applications, and whether plaintiff was reasonably diligent in proceeding toward an actual or constructive reduction of his invention to practice. Plaintiff's testimony to that effect is adequately corroborated by two other witnesses -- Keith Yeisley and Marina Larson -- as well as documents made contemporaneously with the inventive process. On the record before the court, defendants have failed to prove by clear and convincing evidence that Claim 10 of the '572 Patent is invalid due to anticipation under 35 U.S.C. § 102(e).

2.

Defendants also move for summary judgment on their affirmative defense of invalidity for obviousness under 35 U.S.C. § 103(a). A patent is invalid for obviousness if "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). Although the ultimate determination of obviousness is a question of law, it is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *See Riverwood Int'l Corp. v. Mead Corp.*, 212 F.3d 1365, 1366 (Fed. Cir. 2000), *citing Graham v. John Deere Co.*, 383 U.S. 1, 13-14, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

Here, there is a genuine dispute regarding the scope and content of the prior art. In particular, there is a fact question as to the date of invention and which, if any, of the prior art references asserted by defendants predate the date of invention. In light of this dispute, summary judgment on

the issue of obviousness is not appropriate. *See, e.g. KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427, 127 S.Ct. 1727, 1746, 167 L.Ed.2d 705 (2007) (summary judgment proper only where "the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute[.]"); *Judkins v. HT Window Fashions Corp.*, 624 F.Supp.2d 427, 438 (W.D. Pa. 2009) (dispute over the priority date of prior art precludes summary judgment on the issue of invalidity for obviousness).

3.

Likewise, defendants are not entitled to summary on their affirmative defense of invalidity for lack of a written description under 35 U.S.C. § 112, ¶ 1. Under this statute:

The [patent] specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112, ¶ 1. To satisfy the written description requirement, "the applicant must 'convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate that by disclosure in the specification of the patent."

Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341, 1347 (Fed. Cir. 2011), *quoting Carnegie Mellon Univ. v. Hoffman-La Roche, Inc.*, 541 F.3d 1115, 1112 (Fed. Cir. 2008). The applicant need not spell out every detail of the invention in the specification. *See LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). Rather, "only enough must be included to convince a person of skill in the art that the inventor possessed the invention[.]" *Id.*

Compliance with the written description requirement of section 112, ¶ 1 is a question of fact. *Centocor Ortho Biotech*, 636 F.3d at 1347.

Defendants contend that the '572 Patent does not satisfy the written description requirement because the patent does not expressly teach that the invention extends to lenses that create optical powers by diffraction. (*See* Def. MSJ Br. at 28). In support of that argument, defendant relies on the supplemental report of their expert, Dr. Allen L. Cohen, who cursorily states that "one of ordinary skill in the art would not understand the '572 Patent to disclose anything about diffraction." (Def. MSJ App., Exh. 11 at 323). Plaintiff counters with evidence from physics text books, prior art, and other opinions offered by Dr. Cohen in this litigation that diffractive principles are well-established in the scientific community, and that a person skilled in the art of optics would understand that "optical power" includes both diffractive and refractive optical power. (*See* Plf. MSJ App., Exh. 15 at 185-201, Exh. at 80 at 690, Exh. 84 at 723-24 & Exh. 85 at 738-39). While the expert opinion proffered by defendants constitutes some evidence that the '572 Patent fails the written description requirement, it falls far short of the clear and convincing evidence required for defendants to prevail on this affirmative defense at the summary judgment stage.

C.

Finally, defendants seek summary judgment on their affirmative defenses of laches, estoppel, and failure to mark, and on the issue of willful infringement. (*See* Def. MSJ Br. at 29-38). Plaintiff also moves for partial summary judgment on the defenses of laches and estoppel. (*See* Plf. MSJ Br. 7-19). All these issues relate to the recovery of damages. Where, as here, there is a genuine dispute as to the threshold issue of liability, issues related to damages are best left for trial. Therefore, the court should deny summary judgment on all remaining issues relating to damages. *See JDB Med.*,

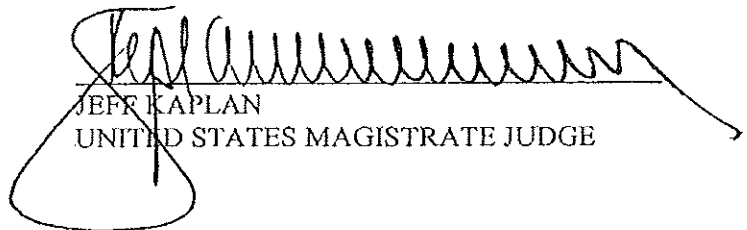
Inc. v. Sorin Group, Nos. 07-CV-00350-REB-CBS & 07-CV-00591-REB-CBS, 2008 WL 791938 at *2 (D. Colo. Mar. 20, 2008) (declining to decide motion for partial summary judgment regarding damages because the "piecemeal resolution" of that issue would neither simplify nor extenuate the evidence presented at trial).

RECOMMENDATION

Defendants' motion for summary judgment [Doc. #180] and plaintiff's motion for partial summary judgment [Doc. #182] should be denied.

A copy of this report and recommendation shall be served on all parties in the manner provided by law. Any party who objects to any part of this report and recommendation must file specific written objections within 14 days after being served with a copy. *See* 28 U.S.C. § 636(b)(1); FED. R. CIV. P. 72(b). In order to be specific, an objection must identify the specific finding or recommendation to which objection is made, state the basis for the objection, and specify the place in the magistrate judge's report and recommendation where the disputed determination is found. An objection that merely incorporates by reference or refers to the briefing before the magistrate judge is not specific. Failure to file specific written objections will bar the aggrieved party from appealing the factual findings and legal conclusions of the magistrate judge that are accepted or adopted by the district court, except upon grounds of plain error. *See Douglass v. United Services Automobile Ass'n*, 79 F.3d 1415, 1417 (5th Cir. 1996).

DATED: September 2, 2011.


JEFF KAPLAN
UNITED STATES MAGISTRATE JUDGE